Clinical Trials

ONCOLOGY SPECIALISTS OF CHARLOTTE
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NON-SMALL CELL LUNG CANCER – 4 Studies NSCLC

Study 1 LUNG

Novocure EF-36/Keynote B36: A Pilot, single arm, open-label study of Tumor Treating Fields (TTFields, 150 kHz) concomitant with Pembrolizumab for First Line Treatment of Advanced Metastatic Intrathoracic NSCLC.

Who's Eligible:

- Histologically or cytologically confirmed de novo diagnosis of Stage III/Metastatic intrathoracic NSCLC (cannot have EGFR activating mutation or ALK translocation). Also, has a PD-L1 positive tumor (TPS ≥ 1%).
- No prior treatments for NSCLC. Palliative treatment is allowed.
- Age 22+
- Have no history of prior malignancy EXCEPT basal cell carcinoma, superficial bladder cancer, squamous cell carcinoma, or in situ cervical cancer, or undergone potentially curative therapy with no evidence of disease recurrence for 5 years since initiation of said therapy.

Study 2 LUNG

BMS CA116-003: Phase 2, Open-label, Randomized study of MORAb-202, a folate receptor antibody drug conjugate in patients with metastatic Non-small Cell Lung Cancer (NSCLC) Adenocarcinoma (AC) AFTER progression on prior therapies.

Who's Eligible:

- Histologically or cytologically documented metastatic NSCLC AC.
- Participants with known targetable genetic alterations in the metastatic setting after receiving at least 1 approved targeted therapy AND no more than 3 prior lines of systemic therapy (including no more than 1 line of chemotherapy).
- Participants without genetic alterations or unknown genetic alterations in the metastatic setting after receiving: 1 prior line of therapy if platinum-doublet chemotherapy and anti-PD-1/PD-L1 were given concurrently OR 2 prior lines of therapy if platinum-doublet chemotherapy and anti-PD-1/PD-L1 were given sequentially.
- Age 18+

Study 3 LUNG

Regeneron R2810-ONC-2045 Phase 1/2 Study Of Cemiplimab (Anti-PD-1 Antibody) In Combination With BNT116 (FixVac Lung) Versus Cemiplimab Monotherapy In First-Line Treatment Of Patients With Advanced Non-Small Cell Lung Cancer (NSCLC) With Tumors Expressing PD-L1 ≥50%

Who's Eligible:

- Age 18+
- Patients with Non-Squamous or Squamous histology with Stage IIIB/IIIC disease who are not candidates for surgical resection or definitive chemoradiation.
- Expression of PD-L1 in ≥ 50% of tumor cells.

Study 4 LUNG

Atreca ATRC-101-A01: Phase 1b Dose Escalation and Expansion Trial to Investigate the Safety, Tolerability, Pharmacokinetics, and Biological Activity of ATRC-101 as Monotherapy and in Combination with Other Anticancer Agents in Adults with Advanced Solid Malignancies

Who's Eligible:

- Age 18+
- 2 open cohorts – ATRC-101 monotherapy and ATRC-101 + Pembrolizumab
- For the monotherapy cohort:
    - Inoperable, locally advanced, or metastatic breast cancer, NSCLC, colorectal cancer, ovarian cancer, or acral melanoma that is refractory to standard therapy or for which no standard therapy exists.
- For the ATRC-101 + Pembrolizumab cohort:
    - Inoperable, locally advanced or metastatic NSCLC, colorectal cancer, melanoma (with the exception of uveal melanoma), hepatocellular carcinoma, head and neck squamous cell carcinoma, esophageal squamous cell carcinoma, urothelial carcinoma, or triple-negative breast cancer with prior or ongoing anti-PD-1 or anti-PD-L1 treatment and have progressed or achieved stable disease for a minimum of 2 months.
- Women of childbearing potential (WOCBP) and fertile males with partners who are WOCBP must use highly effective contraception (per CTFG 2014) from first dose and through 90 days after final dose of investigational product.

PROSTATE CANCER – 2 Studies

Study 1 PROSTATE

Myovant MVT-601-058 ORGOVYX: Phase 4, Multi-Center, Prospective, Observational study of patients being treated with Orgovyx

Who's Eligible:

- Patients aged 18 or older diagnosed with prostate cancer and initiating treatment with ORGOVYX at the time of enrollment or within the 1 month prior to enrollment and who remain on treatment at enrollment
- Patients who have reviewed and signed the informed consent form (ICF)
- Patients who are willing and able to complete PRO assessments during the study

Study 2 PROSTATE

Myovant MVT-601-056 REPLACE: Relugolix Versus Leuprolide in Patients with Prostate Cancer: A Randomized, Open-Label Study to Assess Major Adverse Cardiovascular Events (REPLACE-CV)

Who's Eligible:

- Age ≥ 18 years
- Histologically or cytologically confirmed diagnosis of Adenocarcinoma of the prostate
- Patients with high-risk cardiovascular disease defined as prior history of MACE (myocardial infarction, stroke, coronary revascularization [including percutaneous

procedures] or revascularization affecting cerebral blood flow [including carotid procedures]) > 1 month before enrollment in the study;

- OR Patients with ≥ 3 of the following cardiovascular risk factors:
    - Age (≥ 55 years of age)
    - Hypertension defined as self-reported high blood pressure, or use of a blood pressure-lowering medication
    - Diabetes defined as self-reported diabetes or use of hypoglycemic medication
    - Dyslipidemia defined as self-reported high cholesterol or use of a lipid-lowering medication
    - Current cigarette use, defined as smoking within the year prior to the screening visit
    - Family history of cardiovascular disease, defined as a myocardial infarction or stroke or coronary revascularization or revascularization affecting cerebral blood flow (i.e., carotid procedures) or sudden death in a first-degree relative < 60 years old

MYELODYSPLASTIC SYNDROME/MYELOFIBROSIS (MDS/MF)

Connect Myeloid AZA-MDS-006: Connect® Myeloid: The Myelofibrosis (MF), Myelodysplastic Syndromes (MDS) and Acute Myeloid Leukemia (AML) Disease Registry
Who's Eligible:

- 3 open cohorts – Treated Low-Risk MDS (LR-MDS), Treated Myelofibrosis (MF), and Newly Diagnosed Low-Risk MDS (LR-MDS)
- For Treated LR-MDS cohort:
    - Age: 18+
    - Patients who have initiated their first active treatment regimen containing at least one non-ESA therapy, within 90 days prior to ICF.

        - Active treatment for LR-MDS includes, but is not limited to ATG, eltrombopag, HMAs, IST, lenalidomide, and luspatercept
        - Supportive care, such as transfusions, antibiotics, antivirals, iron chelators, EPO, ESA, growth factors (G-CSF/GM-CSF), tumor lysis prophylaxis are not considered active treatments.
- For Treated Myelofibrosis cohort:
    - Age: 18+
    - Patients who initiated their first active systemic treatment for MF and/or MF-related cytopenias within 90 days prior to the date of ICF signature. This cohort allows the enrollment of subjects with a diagnosis of MDS/MPN overlap syndromes.
        - Active, systemic treatment for MF may include, but is not limited to hydroxyurea, JAK inhibitors, hypomethylating agents, interferon agents, and IO agents.

        - Treatment for MF-related cytopenias may include but is not limited to steroids, ESA, danazol, lenalidomide, pomalidomide, thalidomide.
    - Note: patients who have been on an ESA for anemia and then begin first active systemic treatment are eligible. If a patient has initiated and stopped therapy within the 90-day period due to an adverse event, they are eligible if they have not initiated a second line of therapy.
    - MDS/MPN overlap syndromes include: Chronic myelomonocytic leukemia (CMML), Atypical chronic myeloid leukemia, BCR-ABL1 negative (aCML), Myelodysplastic/myeloproliferative neoplasm with ring sideroblasts and thrombocytosis (MDS/MPN-RS-T), Myelodysplastic/myeloproliferative neoplasm, unclassifiable (MDS/MPN)
- For Newly Diagnosed LR-MDS cohort:
    - Newly diagnosed primary or secondary disease. To be considered "newly diagnosed," a patient's confirmed diagnosis must be made no more than 60 days prior to the date of ICF signature. (An additional 5-day window [i.e., up to 65 days prior to the date of ICF signature] may be allowed in special circumstance upon sponsor approval)
    - Age: 18+

For Enrollment or More Information, contact clinical trials research coordinator at DJL Research in Charlotte 704-247-9179, x-207